

**SELF-EXPANDING STENT AND STENT DELIVERY SYSTEM
FOR TREATMENT OF VASCULAR DISEASE**

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Background of the Invention

Cross-Reference to Related Applications(s)

10 This application claims the benefit of U.S. Patent Application Serial No. 10/651,569 (Attorney Docket No. CRD5035), filed on August 29, 2003, entitled, "Self-Expanding Stent And Stent Delivery System For Treatment Of Vascular Stenosis.

Field of the Invention

15 This invention relates to intravascular stents, stent delivery systems, and methods of using a stent for treating a stenosis or for covering an aneurysm within a blood vessel. More particularly, this invention relates to a very small, self-expanding stent which may be used for percutaneous transluminal angioplasty of occluded blood vessels or for providing a cover for an aneurysm within the brain of a patient.

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Description of the Prior Art

On a worldwide basis, nearly one million balloon angioplasties are performed annually to treat vascular diseases such as blood vessels that are clogged or narrowed by a lesion or stenosis. The objective of this procedure is to increase the inner diameter of 25 the partially occluded blood vessel lumen. In an effort to prevent restenosis without

requiring surgery, short flexible cylinders or scaffolds, referred to as stents, are often placed into the blood vessel at the site of the stenosis.

Stents are typically made of metal or polymers and are widely used for reinforcing diseased blood vessels. Some stents are expanded to their proper size using a balloon catheter. Such stents are referred to as "balloon expandable stents". Other stents, referred to as "self-expanding stents", are designed to automatically expand when released. Both balloon expandable stents and self-expanding stents are generally compressed onto a small diameter catheter and are deployed within a blood vessel.

Several types of balloon catheters have been disclosed in the prior art. One such balloon catheter is disclosed in U.S. Patent No. 5,843,090, entitled "Stent Delivery Device," which balloon catheter is used as a stent delivery device. U.S. Patent No. 5,639,274, entitled "Integrated Catheter System for Balloon Angioplasty and Stent Delivery," discloses an integrated catheter system including a stent deployment catheter and a balloon angioplasty catheter.

Recently, filters mounted on the distal end of guidewires have been proposed for intravascular blood filtration during balloon angioplasty and the delivery of vascular stents. One such filter is disclosed in U.S. Patent No. 6,168,579, entitled "Filter Flush System and Methods of Use." This patent discloses a filter flush system for temporary placement of a filter into a blood vessel. The filter system includes a guidewire for carrying an expandable filter which is collapsed to pass through the lumen of a guiding catheter and is then be expanded upstream of a stenosis prior to angioplasty or to the placement of a stent. U.S. Patent Application Publication No. 2002/0115942, entitled "Low Profile Emboli Capture Device," discloses an emboli capture device comprised of a

filter and a self-expanding stent. The self-expanding stent is attached to the filter in order to open the filter when the emboli capture device is placed within an artery.

Self-expanding stents have generally been compressed onto the outer circumference of a delivery catheter and are then held in the compressed state by an outer 5 catheter which surrounds both the delivery catheter and the stent. As the compressed stent is moved distally out of the distal end of the outer catheter, the stent begins expanding and expands until contact is made between the outer surface of the stent and the inner surface of the wall of a vessel. One problem with a self-expanding stent of this type is that once the stent has expanded within the vessel, it is very difficult to remove the 10 stent or to reposition the stent to a different location within the vessel.

Another form of a self-expanding stent and delivery system is disclosed in U.S. Patent Application Serial No. 10/651,605 (Attorney Docket No. CRD5034), entitled, “Self-Expanding Stent And Stent Delivery System With Distal Protection,” filed on August 29, 2003; and U.S. Patent Application Serial No. 10/651,569 (Attorney Docket 15 No. CRD5035), entitled, “Self-Expanding Stent And Stent Delivery System For Treatment Of Vascular Stenosis,” filed on August 29, 2003. Both of these patent applications disclose a stent and stent delivery system in which the distal end of the stent may be expanded into contact with the vessel wall by partially withdrawing the outer catheter from the stent. The proximal end of the stent may be maintained in a 20 compressed form. If it is then determined that the distal end of the stent is properly positioned within the vessel, the outer catheter may be completely withdrawn permitting the proximal end of the stent to expand into contact with the vessel wall. On the other hand, if after the distal end of the stent is expanded into contact with the vessel wall it is

determined that the stent should be withdrawn, or repositioned, the outer catheter may be moved distally back over the distal end of the stent to cause the distal end of the stent to again become compressed within the outer catheter. The stent, contained within the outer catheter, may be repositioned to a different location within the vessel and the same 5 procedure may again be followed for positioning the stent at the new location.

Summary of the Invention

In accordance with the present invention, there is provided a self-expanding stent and stent delivery system. The stent delivery system includes an elongated delivery 10 catheter having a lumen extending therethrough. Disposed within the lumen of the delivery catheter is an elongated core member. The elongated core member includes a proximal cylindrical member and a distal cylindrical member, both disposed at the distal portion of the core member. The distal cylindrical member is generally positioned distally of the proximal cylindrical member and spaced apart from the proximal 15 cylindrical member to define a gap having a predetermined length. A self-expanding stent comprised of a small diameter skeletal tubular member having a thin wall. With a plurality of cells which are formed by a plurality of interconnected strut members. A cylindrical anchor member is placed on one of the strut members and has a length less than the length of the gap between the proximal cylindrical member and the distal 20 cylindrical member. The self-expanding stent is mounted and compressed onto the elongated core member and is aligned such that the cylindrical anchor member is interlocked within the gap between the proximal cylindrical member and the distal cylindrical member to thereby retain the stent in a position on the elongated core

member. An actuatable retaining ring member is placed around the distal end of the self-expanding stent and served to hold the distal end of the stent in its compressed state.

Upon actuation, such as by heating, the retaining ring member yields thereby releasing the distal end of the compressed stent with the result that the stent expands into contact
5 with the inside wall of a blood vessel.

In accordance with another aspect of the present invention, there is provided another retaining ring which is disposed about the proximal portion of the self-expanding stent which serves to retain the proximal portion of the stent thereby preventing this portion of the stent to be expanded until such time as the retaining ring is actuated.

10 In accordance with still another aspect of the present invention, the actuatable retaining rings are formed of a material which when heated yields to thereby become severed in order to permit the compressed, self-expanded stent to expand into contact with the walls of a vessel.

In accordance with still a further aspect of the present invention, the stent delivery
15 system includes a heating element positioned in proximity to the actuatable retaining rings and also includes electrical conductors connected to the heating element for, upon being energized, causing the heating element to heat the actuatable retaining rings with the result that the retaining rings become severed to permit the self-expanding stent to expand into contact with the walls of a vessel.

20 In accordance with still a further aspect of the present invention, the actuatable retaining rings are comprised of a polymeric material, such as a hot melt polymer, and the heating element takes the form of a resistive heating element.

In accordance with another aspect of the present invention there is provided a delivery catheter, an elongated core member slidably disposed within the delivery catheter, a self-expanding stent mounted on the elongated core member in a compressed state, and an actuatable retaining ring, for upon actuation, releasing the self-expanding stent to permit the stent to expand against the wall of a vessel.

In accordance with yet another aspect of the present invention, there is provided a self-expanding stent and stent delivery system including a balloon catheter comprised of an elongated catheter having a delivery lumen. The balloon catheter includes an expandable balloon mounted on the distal section of the elongated catheter. An elongated core member is slidably disposed within the delivery lumen of the elongated catheter. A stop member extends radially outward from the core member, and a self-expanding stent is mounted on the elongated core member engaging the stop member so that the stent can be moved through the delivery lumen when the elongated core member is moved through the delivery lumen.

In accordance with a further aspect of the present invention, there is provided a method of treating a stenosis including the steps of advancing a compressed self-expanding stent mounted on an elongated core member into a vessel of the body until the self-expanding stent is properly positioned within the vessel, actuating a stent retention ring positioned around the stent to thereby cause the retaining ring to sever and release the compressed self-expanding stent allowing the stent to expand within the vessel, and then withdrawing the elongated core member from the vessel.

In accordance with still a further aspect of the present invention, the method includes the step of heating the retaining ring to thereby cause the retaining ring to yield resulting in the release of the compressed self-expanding stent.

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Brief Description of the Drawings

Figure 1 is a partially sectional view of an integrated balloon catheter and a self-expanding stent mounted;

Figure 2 is an oblique view of the self-expanding stent of Figure 1 mounted on a
10 core wire and held in a compressed state by two actuatable retaining rings;

Figure 2a is an oblique view of the two actuatable retaining rings and
corresponding heating elements;

Figure 3 is a sectional view of the integrated balloon catheter and self-expanding
stent of Figure 1 within a blood vessel prior to expansion of the balloon and the self-
15 expanding stent;

Figure 4 is a sectional view of the integrated balloon catheter and self-expanding
stent positioned within a blood vessel with the balloon fully expanded;

Figure 5 is a sectional view of the integrated balloon catheter and self-expanding
stent with the balloon deflated and the outer catheter being moved proximally and with
20 the distal actuatable retaining ring severed to release the stent thereby allowing the distal
end of the stent to expand within the blood vessel;

Figure 6 is a sectional view of the proximal actuatable retaining ring severed thereby permitting the self-expanding stent to become fully expanded within the blood vessel;

- Figure 7 is a sectional view of the balloon catheter and elongated core wire
5 withdrawn proximally from the self-expanding stent; and,

Figure 8 is an elevational view of the self-expanding stent within the blood vessel with the balloon catheter and elongated core wire removed from the blood vessel.

Description of the Preferred Embodiment

10 Figure 1 illustrates an integrated balloon catheter and self-expanding stent including a balloon catheter 2 comprised of an outer catheter 3 having a Luer connector coupling member 5. The coupling member 5 includes a delivery port 6 which communicates with a delivery lumen 7, which in turn, extends throughout the length of the balloon catheter 2. The coupling member 5 also includes an inflation port 8 used to 15 inflate and expand the balloon 9 disposed about the distal portion 10 of the outer catheter
3. The balloon catheter 2 is sufficiently rigid to be pushed distally through a blood vessel, yet flexible enough to traverse the narrow and tortuous blood vessels within a blood vessel, such as a blood vessel within the brain.

Slidably disposed within the delivery lumen 7 is an elongated core wire 14. 20 Disposed about the elongated core wire 14 are a proximal cylindrical member 16 and a distal cylindrical member 18, both of which may take the form of a helical coil. A self-expanding sent 20 is mounted on the elongated core wire 14. The proximal and distal cylindrical members 16, 18 are spaced apart to form a gap between the cylindrical

member and serve as stop members extending radially outward from the core wire 14 to engage the stent 20 in order to prevent longitudinal movement of the stent relative to the core wire 14. A proximal actuatable retaining ring 19 and a distal actuatable retaining ring 21 extend around the proximal and distal portions, respectively, of the stent 20 and 5 serve to restrain the stent in a compressed state. The actuatable retaining rings are caused to yield and then sever upon the application of an electrical current which is applied through a power source 23. The construction and operation of the actuatable retaining rings 19, 21 are shown in more detail in Figures 2 and 2a.

Figure 2 illustrates the self-expanding stent 20 mounted on the elongated core 10 wire 14. Disposed about the elongated core wire 14 is the proximal cylindrical member 16, which preferably takes the form of a helically wound flexible coil. The coil may be formed of metal or of a polymer material. A distal cylindrical member 18 is disposed about the elongated core wire 14 and is positioned distally from the proximal cylindrical member 16. The distal cylindrical member 18 is spaced apart from the proximal 15 cylindrical member 16 such that the space between the proximal and distal cylindrical members 16, 18 forms a gap 42. The distal cylindrical member 18 is also preferably a helically wound flexible coil.

The self-expanding stent 20 may take on many different patterns or configurations. Examples of such self-expanding stents are disclosed in U.S. Patent 20 Application Serial No. 10/163,116, entitled, "Intravascular Stent Device," and filed on June 5, 2002, and U.S. Patent Application Serial No. 10/163,248, entitled, "Intravascular Stent Device," filed on June 5, 2002, both assigned to the same assignee as the present patent application. The stent 20 is preferably coated with a bioactive agent, such as

heparin or rapamycin, to prevent restenosis within the vessel. Examples of such coatings are disclosed in U.S. Patent Nos. 5,288,711; 5,516,781; 5,563,146 and 5,646,160.

The self-expanding stent 20 is preferably laser cut from a nitinol tube to form a skeletal tubular member. The skeletal tubular member has a small diameter and a thin
5 wall which defines a plurality of cells formed by a plurality of interconnected strut members. The nitinol is treated so as to exhibit superelastic properties at body temperature. Additionally, the stent 20 includes proximal and distal strut members 44, 46 coupled to the proximal and distal sections 48, 50 of the stent. The proximal and distal strut members 44, 46 are cut to form threads on the strut members during the laser-cutting
10 of the stent 20. Radiopaque coils are then wound onto the threads of the proximal and distal strut members 44, 46 to form anchor members 52. Preferably, the stent 20 includes eight anchor members 52. When the self-expanding stent 20 is mounted on the elongated core wire 14, the anchor members 52 align with and are disposed within the first gap 42 thus coupling the stent to the elongated core wire 14. In this configuration, the stent 20
15 can be moved distally through the delivery lumen 7 of the balloon catheter 2 by moving the core wire 14 distally. The self-expanding stent 20 is described in more detail in U.S. Patent Application, Serial No. 10/608,659 (Attorney Docket No. CRD5001CIP), entitled “Expandable Stent with Radiopaque Markers and Stent Delivery System,” filed on June 27, 2003 and assigned to the same assignee as the present patent application.
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Figures 2 and 2a illustrate in more detail the actuatable retaining rings 19, 21 which serve to hold the self-expanding stent in its compressed state. The actuatable retaining rings 19, 21 are preferably formed from a filament of a hot melt polymer, such as a polymer marketed by Minnesota Mining and Manufacturing under the trade name Jet

Melt, Catalog No. 3783-TC, however, various other biocompatible thermoplastic polymers which exhibit the characteristic of melting, or decreasing yield strength when heat is applied, could be used for the rings. The application of heat to the polymer causes the polymer to exhibit the characteristic of yielding and ultimately severing to thereby

5 release the compressed stent. The actuatable retaining rings 19,21 serve to clamp the stent onto the elongated core wire 14. Resistive heating elements 25, 27 are placed in proximity to the actuatable retaining rings 19, 21, respectively, and the heating elements are coupled through electrical conductors 28, 29, 30, to the power source 23.

Accordingly, upon application of electrical current to the resistive heating element 27, the

10 heating element 27 generates heat, which in turn, is applied to the corresponding distal actuatable retaining ring 21 causing this retaining ring to yield and then sever thereby releasing the distal portion of the compressed stent 20. Similarly, when electrical current is applied to the resistive heating element 25, this heating element begins to heat and causes the proximal actuatable retaining ring 19 to yield and sever, and in turn, it releases

15 the proximal portion of the stent 20 to expand from its compressed state.

Figure 3 shows the balloon catheter 2 inserted within a blood vessel 58 of the brain of a patient. The balloon catheter 2 includes an expandable balloon 9 disposed about the distal portion 10 of the elongated outer catheter 3. In the preferred embodiment of the present invention, an inflation lumen 60 extends from the inflation port 8 and

20 communicates with the balloon 9. To perform an angioplasty of the blood vessel 58, a fluid is injected into the inflation lumen 60, through the inflation port 8, to thus expand the balloon 9. The operation of the balloon catheter is described in more detail in U.S.

Patent No. 6,585,687, entitled "Inflatable Balloon Catheter Body Construction," assigned to the same assignee as the present patent application.

Typically, the balloon catheter 2 is advanced distally through the blood vessel 58 over a guidewire until it is aligned with a stenosis 62. Then, the guidewire is removed 5 and the elongated core wire 14 is inserted into the delivery lumen 7 of the balloon catheter 2. The self-expanding stent 20 is mounted on the elongated core wire 14 such that the anchor members 52 align with and are disposed within the gap 42, between the proximal and distal cylindrical members 16, 18. In this configuration, the stent 20 is engaged to the core wire 14 so that the stent may be moved proximally and distally 10 through the delivery lumen 7 of the balloon catheter 2.

Figure 4 illustrates the balloon catheter 2 having the expandable balloon 9 fully expanded within the blood vessel 58. Preferably, the balloon 9 is expanded by injecting fluid into the inflation lumen 60 of the balloon catheter. The expanded balloon 9 compresses the stenosis 62 and thus increases the luminal diameter of the blood vessel 15 58.

Figure 5 illustrates the balloon 9 in a deflated configuration and the balloon catheter 2 is moved proximally exposing the distal portion of the stent 20. Initially the distal portion of the stent is held in compression by the actuatable retaining ring 21. When an electrical current is applied to the resistive heating element 27 the distal 20 actuatable retaining ring 21 begins to yield and then becomes severed as illustrated. At this point the distal portion of the stent 20 expands into contact with the vessel wall. After expansion of the distal portion of the stent 20, it is determined that the stent has been improperly positioned, the partially expanded stent may be simply withdrawn back

into the balloon catheter 2. The catheter 2 may then be moved to a new position and the stent may again be moved distally thereby permitting the distal portion of the stent to expand. Since the actuatable retaining ring 21 was severed during the initial placement of the stent, the distal end of the stent will automatically expand into contact with the
5 inside wall of the vessel.

If on the other hand the distal portion of the stent is properly positioned, the balloon catheter 2 is again moved proximally, as illustrated in Figure 6 to also expose the proximal portion of the stent. An electrical current may then be applied to the proximal heating element 25 to thereby cause the heating element 25 to begin heating, which in
10 turn, causes the proximal actuatable retaining ring 19 to yield and become severed. Once the retaining ring 19 severs, the proximal portion of the stent 20 expands into contact with the inside wall of the vessel.
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Figure 7 illustrates elongated core wire 14 entirely withdrawn from the stent 20 and into the lumen of the balloon catheter 2. The elongated core wire 14 carries with it into the lumen the severed actuatable retaining rings 19, 21.
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Figure 8 illustrates the self-expanding stent 20 expanded into the interior of the vessel so as to serve as a scaffold for maintaining patency of the vessel.

A novel system has been disclosed in which a self-expanding stent is mounted on an elongated core member and is slidably disposed within a balloon catheter. Although a
20 preferred embodiment of the present invention has been described, it is to be understood that various modifications may be made by those skilled in the art without departing from the scope of the claims. For example, the actuatable retaining rings 19, 21 could be formed of a material which would be severed by the process of electrolysis, through a

chemical reaction or through another form of electrical activation. Such alternative designs would not depart from the scope of the claims which follow.